K062148

SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 24 2006

NAME OF FIRM:

DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT:

Anne M. Schuler
Sr Regulatory Affairs Associate

DATE PREPARED:

October 23, 2006

TRADE NAME:

DePuy Pinnacle® AltrX™ Acetabular Cup Liner

COMMON NAME:

Acetabular Cup Liner

CLASSIFICATION:

CFR 888.3358 Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis, Class II device

CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis, Class II device

DEVICE PRODUCT CODE:

87 LPH, LZO

SUBSTANTIALLY EQUIVALENT DEVICE:

DePuy Pinnacle® Acetabular Cup System ESL Marathon™ Polyethylene liners (K033273, cleared May 6, 2004)

DePuy Pinnacle® Acetabular System (K000306, cleared March 23, 2000)

Wright Medical LINEAGE® A-CLASS™ Poly Liner (K052026, cleared Dec 5, 2005)

DEVICE INFORMATION:

A. DEVICE DESCRIPTION

The Pinnacle AltrX Acetabular Cup Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner

manufactured from cross-linked ultra high molecular weight polyethylene (UHMWPE), which locks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

The subject Pinnacle AltrX liners are cross-linked UHMWPE acetabular cup liners that are available in a neutral, lateralized neutral, lipped or lateralized face-changing orientation. The liners have inner diameters (ID) intended for use with modular, unipolar, self-centering (bipolar), M-Spec or ceramic femoral heads within the 28mm-48mm size range. The outer diameters (OD) are geometrically the same as other Pinnacle Acetabular Cup Liners, in a 44mm-76mm size range offering.

The following marketing claim will be made for the Pinnacle Altrx liner:

AltrX™ UHMWPE liners reduce wear by 53% compared to previously cleared DePuy Marathon® UHMWPE liners while maintaining similar physical and mechanical properties as Marathon® UHMWPE. In addition, AltrX™ UHMWPE liners reduce wear by 92% compared to previously cleared conventional non-crosslinked UHMWPE liners.

An in-vitro hip simulator wear study was conducted to support these wear claims. The study was conducted using test devices identified as AltrX™ Polyethylene liners and two control devices identified as Marathon® Polyethylene liners and Enduron® Polyethylene liners. The test and control liners were manufactured by DePuy Orthopaedics by a ram extrusion process. The test and control liners had a thickness of 0.374 inches with a 28mm inner diameter and were gas plasma sterilized prior to the study.

Test and control liners were tested for 6 million cycles using an orbital bearing hip wear test machine manufactured by Shore Western Manufacturing Inc. The articulating component for both the test and control liners was a 28mm CoCr femoral head manufactured by DePuy Orthopaedics. The lubricant used in the study was 90% bovine serum with 0.2% NaN_3 and 20mM EDTA. The wear rates determined at the conclusion of the study were 43.6 ± 5.0 mg/million cycles (mg/MC) for the Enduron control, 7.3 ± 1.0 mg/MC for the Marathon control and 3.4 ± 0.2 mg/MC for the AltrX test material.

Note: Reduced Wear Claims are based on the results of in-vitro hip wear simulator tests which have not been shown to quantitatively predict clinical wear performance

B. INTENDED USE AND INDICATIONS

Intended Use

The subject Pinnacle AltrX UHMWPE Liners are intended to be used with the DePuy Pinnacle metal acetabular shells, modular femoral heads, unipolar femoral heads, M-Spec heads, bi-polar self-centering heads and ceramic heads to resurface the acetabular socket in cementless total hip arthroplasty.

Indications

The Pinnacle AltrX Acetabular Cup Liner is indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle AltrX is indicated for use with the Pinnacle Acetabular Cup in cementless application.

C. BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle AltrX Acetabular Cup Liners have the same design, intended use, manufacturing method, sterilization and packaging as the Pinancle Marathon Acetabular Liners cleared in K033273 and K000306. Mechanical testing shows that the AltrX liners perform similarly to the Marathon liners and exhibit less wear in hip simulator testing. Based on similarities in design, intended use, manufacturing method, sterilization and packaging DePuy believes that the Pinnacle® AltrX™ Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle® Marathon™ Liners and to the previously cleared Wright Medical LINEAGE® A-CLASS™ Poly Liner which is similar in design, manufacturing method and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Anne M. Schuler
Sr. Regulatory Affairs Associate
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana

OCT 2 4 2006

Re: K062148
Trade/Device Name: DePuy Pinnacle Altrx™ Acetabular Cup Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: July 26, 2006
Received: July 27, 2006

Dear Ms. Schuler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062148
Device Name: DePuy Pinnacle AltrX™ Acetabular Cup Liners

Indications for Use:

The Pinnacle AltrX™ Acetabular Cup Liners are indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle AltrX Acetabular Cup Liners are indicated for use with the Pinnacle Acetabular Cups in cementless applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

0000003

510(k) Number K062148